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EXAMINER

RAO, MANJUNATH N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/836,613

Applicant(s)

HOPWOOD ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36,60-71,85 and 96-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-36,60-71,85 and 96-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 19-36, 60-71, 85, 96-99 are currently pending and under consideration in this application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/077354, filed on 4-22-1999.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Objections

Claim 70 is objected to because of the following informalities: Claim 70 recites the phrase "produced by expression of a nucleic acid molecule according to claim 35". However, claim 35 is not directed to a nucleic acid. Therefore claim 70 is improperly dependent on claim 35. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-36, 60-71, 85, 96-99 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claims are drawn to recombinant mammalian α -N-acetylglucosaminidase or a fragment or a derivative thereof. It is not clear to the Examiner as to whether the fragment or the derivative has to have the same α -N-acetylglucosaminidase activity rendering the claims indefinite. A perusal of the specification provides a definition of the derivative. However, the definition is not clear regarding the functional aspect of the derivative.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the phrase "in substantially pure form". The metes and bounds of the above phrase is not clear to the Examiner. A perusal of the specification did not yield a specific definition for the phrase "substantially pure".

Claims 29, 61, 96-99, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29, 61, 96-99 recite the phrase "amino acids substantially the same as". The metes and bounds of the phrase "substantially the same as" is not clear to the Examiner. A perusal of the specification did not yield a specific definition for the above phrase thus rendering the claim indefinite.

Claims 32-34, 67-69, and 99, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32-34, 67-69, and 99 recite the phrase "amino acid

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sequence substantially as set forth in". The metes and bounds of the phrase "substantially as set forth in" is not clear to the Examiner. A perusal of the specification did not yield a specific definition for the above phrase thus rendering the claim indefinite.

Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 71 recites the phrase "a patient suffering from α -N-acetylglucosaminidase". It is not clear to the Examiner as to what applicants mean by a patient suffering from an enzyme. It appears that applicants intended to recite "a patient suffering from α -N-acetylglucosaminidase deficiency or disorder". If this is so amending the claim accordingly will overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-36, 60-68, 70-71, 85, 96-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enzyme having α -N-acetylglucosaminidase activity and an amino acid sequence SEQ ID NO:2 or an amino acid sequence that is 80% identical to SEQ ID NO:2 or a pharmaceutical composition comprising such enzymes, does not reasonably provide enablement for such an enzyme isolated from any or all sources, having an amino acid sequence identity that is either 40% or 60% of SEQ ID NO:2 or an amino acid sequence that is encoded by a polynucleotide capable of hybridizing to SEQ ID

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NO:1 or 3 under low stringency conditions or an amino acid sequence that is substantially the same as that of a human α -N-acetylglucosaminidase or fragments or derivatives of such enzymes, including mutants and variants and pharmaceutical compositions comprising the above enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 19-36, 60-68, 70-71, 85, 96-99 are so broad as to encompass any α -N-acetylglucosaminidase isolated from any or all sources, comprising an amino acid sequence identity that is either 40% or 60% of SEQ ID NO:2 or an amino acid sequence that is encoded by a polynucleotide capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions or an amino acid sequence that is substantially the same as that of a human α -N-acetylglucosaminidase or fragments or derivatives of such enzymes and pharmaceutical compositions comprising the above enzymes. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of α -N-acetylglucosaminidase broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be

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tolerated in a protein's amino acid sequence and still obtain the desired activity, requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of a single α -N-acetylglucosaminidase from a single source.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any α -N-acetylglucosaminidase with 40% or 60% amino acid sequence identity to the enzyme of SEQ ID NOS:2 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the glucosaminidase activity; (B) the general tolerance of α -N-acetylglucosaminidases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any α -N-acetylglucosaminidase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including α -N-acetylglucosaminidases from all or any sources and with an enormous number of amino acid modifications of the α -N-acetylglucosaminidase with SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of α -N-acetylglucosaminidase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 19-36, 60-68, 70-71, 85, 96-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19-36, 60-68, 70-71, 85, 96-99 are directed to polypeptide fragments corresponding to portions of the sequence of SEQ ID NO:2 and variants of SEQ ID NO:2. Claims 19-36, 60-68, 70-71, 85, 96-99 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:2 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in SEQ ID NO:2 and fragments of SEQ ID NO:2 that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID

NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences claimed, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structure and function (specifically fragments and derivatives). Therefore many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 19-20, 26-29, 32-36, 85, 96, 99 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhao(a) et al. (American Journal of Genetics, 1995, Vol. 57: A185, Abstract 1059). This rejection is based on the public availability of a printed publication reporting the

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cloning of a mammalian DNA encoding alpha-N-acetylglucosaminidase (NAG) enzyme . This rejection is also based on the breadth of the claims as written.

Claims 19-20, 26-29, 32-36, 85, 96, 99 of the instant application are drawn to a recombinant mammalian α -N-glucosaminidase or a fragment or a derivative of the same, in substantially pure form, expressed in mammalian cells, wherein the mammalian cell is capable of N-glycosylating the enzyme, wherein the NAG enzyme is in a glycosylated form and has a molecular weight of at least 79kDa to 89kDa when determined by SDS/PAGE and wherein the amino acid sequence of the NAG is substantially the same as that of human NAG and wherein the amino acid sequence is substantially as set forth in SEQ ID NO:2 or at least 40% or 60% or 80% similar to SEQ ID NO:2 and wherein the enzyme is produced by expression of a nucleic acid which encodes the enzyme or is complementary to a sequence encoding the enzyme and is carried in a vector capable of expression in a eukaryotic or prokaryotic cell, wherein the enzyme has an amino acid sequence that is 40% similar and encoded by a nucleic acid capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions or wherein the amino acid sequence is substantially the same as that of human NAG.

Zhao(a) et al. disclose a cDNA encoding a mammalian (human) α -N-acetylglucosaminidase and a substantially pure recombinant form of the enzyme. The above reference is not explicit on the glycosylated form of the enzyme or whether it was expressed in a prokaryotic or eukaryotic cell. The reference is also not explicit on the molecular weight of the enzyme and does not disclose the amino acid sequence of the enzyme or that the nucleotide encoding the enzyme is capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions. However, Examiner takes the position that the mammalian enzyme disclosed in the

reference and that claimed in the instant invention are one and the same. Since the enzyme has been isolated from a human source and is a recombinant enzyme, Examiner also takes the position that the glycosylation aspect, molecular weight and the amino acid sequence including the nucleotide sequence which encodes the enzyme are all inherent characteristics and that the enzyme disclosed in the reference and that claimed are one and the same. Therefore, Zhao et al. anticipates claims 19-20, 26-29, 32-36, 85, 96, 99 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20, 26-29, 32-36, 85, 96, 99 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhao(b) et al. (American Journal of Genetics, 1994, Vol. 55: A252, Abstract 1473). This rejection is based on the public availability of a printed publication reporting the cloning of a mammalian DNA encoding alpha-N-acetylglucosaminidase (NAG) enzyme. This rejection is also based on the breadth of the claims as written.

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Claims 19-20, 26-29, 32-36, 85, 96, 99 of the instant application are drawn to a recombinant mammalian α -N-glucosaminidase or a fragment or a derivative of the same, in substantially pure form, expressed in mammalian cells, wherein the mammalian cell is capable of N-glycosylating the enzyme, wherein the NAG enzyme is in a glycosylated form and has a molecular weight of at least 79kDa to 89kDa when determined by SDS/PAGE and wherein the amino acid sequence of the NAG is substantially the same as that of human NAG and wherein the amino acid sequence is substantially as set forth in SEQ ID NO:2 or at least 40% or 60% or 80% similar to SEQ ID NO:2 and wherein the enzyme is produced by expression of a nucleic acid which encodes the enzyme or is complementary to a sequence encoding the enzyme and is carried in a vector capable of expression in a eukaryotic or prokaryotic cell, wherein the enzyme has an amino acid sequence that is 40% similar and encoded by a nucleic acid capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions or wherein the amino acid sequence is substantially the same as that of human NAG.

Zhao(b) et al. disclose a cDNA encoding a mammalian (human) α -N-acetylglucosaminidase and a substantially pure recombinant form of the enzyme. The above reference is not explicit on the glycosylated form of the enzyme or whether it was expressed in a prokaryotic or eukaryotic cell. The reference is also not explicit on the molecular weight of the enzyme and does not disclose the amino acid sequence of the enzyme or that the nucleotide encoding the enzyme is capable of hybridizing to SEQ ID NO:1 or 3 under low stringency conditions. However, Examiner takes the position that the mammalian enzyme disclosed in the reference and that claimed in the instant invention are one and the same. Since the enzyme has been isolated from a human source and is a recombinant enzyme, Examiner also takes the

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position that the glycosylation aspect, molecular weight and the amino acid sequence including the nucleotide sequence which encodes the enzyme are all inherent characteristics and that the enzyme disclosed in the reference and that claimed are one and the same. Therefore, Zhao et al. anticipates claims 19-20, 26-29, 32-36, 85, 96, 99 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-25, 30-31, 60-71, 97-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao(a) et al. and Zhao(b) et al. as applied to claims 19-20, 26-29, 32-36, 85, 96, 99 above, and further in view of the common knowledge in the art of molecular biology.

Claims 21-25, 30-31, 60-71, 97-98 are drawn to the recombinant NAG according to claim 19 expressed in a mammalian (CHO cells), yeast or insect host cells capable of N-glycosylating the recombinant enzyme wherein the recombinant NAG is also expressed as a fusion protein

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with another enzyme, reporter molecule, purification site and or a signal sequence, and to pharmaceutical composition comprising the above recombinant enzyme or an active fragment or derivative produced by expression of a nucleic acid encoding the enzyme and wherein the pharmaceutical composition is used in a method for treating patients suffering from NAG disorder.

Zhao (a) and (b) et al. teach methods of isolating polynucleotides encoding human NAG using the amino acid sequence information of a bovine testis enzyme in conjunction with recombinant techniques such as PCR, DNA cloning and DNA sequencing. The references teach the isolation of the cDNA clone encoding the recombinant form of the human NAG. However, the references are not explicit regarding the host cells used for expression of the recombinant enzyme or the glycosylation status of the recombinant enzyme. While the reference teaches that the deficiency of NAG enzyme under lies type B Sanfilippo syndrome, a mucopolysaccharide storage disorder with profound neurodegeneration, the above references do not teach the use of the recombinant enzyme for treating such disorder.

Using the references of Zhao(a) and Zhao(b) et al., it would have been obvious to one skilled in the art at the time the invention was made to take the cDNA clone taught by the above references and subclone it in any of the host cells prokaryotic or eukaryotic cells, including a mammalian, yeast or insect cell. Since it is well known in the art that eukaryotic cells have the glycosylating machinery as opposed to prokaryotic host cells, it would have been obvious to one of ordinary skill in the art to use a mammalian cell such as CHO cells in order to obtain a recombinant NAG which is N-glycosylated. Similarly, with the well known common knowledge in the art that recombinant proteins can be expressed as fusion proteins with a reporter molecule

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or a purification site in order to monitor either the expression of the recombinant protein or purification of the recombinant proteins, it would have been obvious to one of skill in the art to express the recombinant NAG of Zhao et al. as a fusion protein. As Zhao (a) et al. teach that the deficiency of the above enzyme is the root cause of the type B Sanfilippo syndrome, it would have been obvious to use the recombinant enzyme taught by Zhao(a) et al. or Zhao (b) et al. and prepare pharmaceutical compositions to be used for treatment of NAG related disorders. One of ordinary skill in the art would have been motivated to do so as the above references teach the importance of the enzyme in relation to treat a human disorder. One of ordinary skill in the art would have had a reasonable expectation of success, since the above references teach the importance of the enzyme in human physiology and also provide a cDNA clone for the above enzyme.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art to have performed the claimed invention.

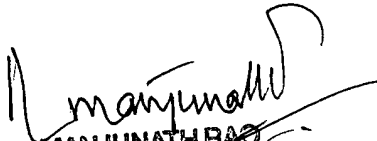
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


MANJUNATH RAO
PATENT EXAMINER
Manjunath N. Rao
12/7/02